



## Frequently Asked Questions (FAQs) for COVID-19 Vaccine Providers

**This running FAQ document will be updated each Monday.**

**Latest update: December 28, 2020**

- Denotes new Q/A
- Language updates in green font

### Administering COVID-19 Vaccines to Patients and Staff

***If someone has already been diagnosed with COVID-19, do they still need to get the vaccine when the time comes for their designated phase?***

According to the CDC, individuals previously diagnosed with acute SARS-CoV-2 infection in the past 90 days may elect to delay vaccination as data suggest that reinfection is unlikely during that period. However, data from clinical trials indicate that mRNA COVID-19 vaccines are safe in persons with evidence of a prior SARS-CoV-2 infection and prior infection is not a contraindication to vaccination. Testing for antibodies prior to vaccination is not recommended. Specific more detailed information from ACIP regarding vaccination in previously infected individuals is available [here](#).

***Are there any timing concerns with receiving the COVID-19 vaccine and timing of administration of any other types of vaccines?***

According to CDC, given the lack of data on the safety and efficacy of the COVID-19 vaccine administered simultaneously with other vaccines, the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If the COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

***If an employee/patient cannot receive the 2<sup>nd</sup> dose of vaccine at the correct time, how many days before or after can the dose be given?***

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 ml each): three weeks (21 days) apart
- Moderna (100 µg, 0.5 ml): one month (28 days) apart

Second doses administered within a period of  $\leq 4$  days from the recommended date for the second dose are considered valid, though doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as

possible but there is no maximum interval between the first and second dose for either vaccine.

***What are the known contraindications for the Pfizer or Moderna vaccines?***

Known contraindications include age <16 years for the Pfizer vaccine and <18 years for the Moderna vaccine. Severe allergic reaction (e.g. anaphylaxis) to any vaccine component is also a contraindication for both the Pfizer and Moderna vaccines.

Anaphylactic reactions in persons who received Pfizer COVID-19 vaccine outside of clinical trials have been reported. While these reports are further investigated, CDC considers a history of severe allergic reaction to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines (as these vaccines contain ingredients in common). Individuals with significant allergies to other substances (such as pets or foods) should be observed for 30 minutes after vaccine administration. More Information available [here](#).

***What are the recommendations regarding either mRNA COVID-19 vaccine for individuals who have a history of anaphylaxis?***

Individuals with history of anaphylaxis to injected or infused medications, including vaccines, may be vaccinated but should receive vaccine in a location where they can receive appropriate care, if necessary. These individuals should be observed for 30 minutes after receiving vaccine. Food, pet and environmental allergies are not a concern. Information from CDC is available [here](#).

A history of mild allergic reaction to a vaccine or injectable therapy, such as localized urticaria alone without signs or symptoms of anaphylaxis, is not a contraindication to vaccination with either mRNA COVID-19 vaccine. In addition, allergic reactions not related to vaccines or injectable therapies (e.g., food, pet, venom, or environmental allergies; allergies to oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine.

***Are there additional clinical considerations for persons who have previously received passive antibody therapy for COVID-19?***

Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of these therapies as well as [evidence](#) suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

***Can immunocompromised people receive the vaccine? If so, are their symptoms worse?***

Yes. Immunocompromised individuals were included in the clinical trials. Those who are immunocompromised may not mount the same level of protection in response to the vaccine as those who are not immunocompromised.

***Is a consent form required for individuals to sign in order to receive the vaccine?***

Written consent is not required. Federal law requires the Emergency Use Authorization information sheet to be provided to individuals before vaccination, but no signature is required. If your facility chooses to use a consent form, the template is available on the Tennessee Department of Health [website](#).

***Will Vaccine Information Statements (VIS) be available at the time of vaccine administration?***

A VIS sheet will not be issued for COVID-19 vaccines under EUA. An EUA information sheet will be issued after EUA approval, and it is required that patients receive this multi-page sheet before vaccination.

***Can you direct me to a summary of talking points to explain vaccine facts to patients?***

The CDC has talking points for patients: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect.html>. There is also a nice summary of clinical considerations for Pfizer and Moderna vaccine administration available [here](#).

- ***If a healthcare worker receives the vaccine and develops fever or mild symptoms after the vaccine, should these individuals isolate and obtain a COVID-19 test? Is there any post-vaccination guidance regarding what employers should do if someone develops potential COVID-19 symptoms?***

If the person is experiencing mild symptoms normally seen following a vaccine, the CDC would not recommend testing at that point. CDC recently released helpful post-vaccine considerations for healthcare personnel available [here](#).

***If Phase 1a1 staff choose not to receive the vaccine when offered, when can they expect another chance to be vaccinated?***

That depends on the employer and their vaccination plan for employees. TN Department of Health encourages all individuals to get the vaccine when it is offered to them, as details about repeat vaccine allocation quantities are still being developed and are dependent on federal allocation and local uptake.

- ***If we have extra doses of the Pfizer vaccine in the vial, can we use that dose?***

DO provide every 0.3ml dose that can be drawn from a vial of the Pfizer vaccine. You MAY NOT combine overfill from multiple vials to achieve an additional dose. Overfill that is <0.3ml must

be discarded.

## Pregnant and Breastfeeding Populations

### ***If a healthcare worker is pregnant, should they receive an mRNA COVID-19 vaccine?***

According to the CDC, pregnant people are at increased risk for severe illness from COVID-19 compared to non-pregnant people based on [what we know now](#). Additionally, pregnant people with COVID-19 might be at increased risk for other adverse outcomes, such as preterm birth. Currently there are no studies on safety and efficacy of COVID-19 vaccines in pregnant women to inform vaccine recommendations. ACIP has stated that pregnant and lactating women **may** receive either mRNA Covid-19 vaccines if they are in a high-risk phase or group. A conversation between the patient and their healthcare provider may help the patient with the decision about taking the vaccine.

### ***Should individuals receive an mRNA COVID-19 vaccine if they are planning to get pregnant?***

There is no recommendation for pregnancy testing before getting a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after an mRNA COVID-19 vaccination.

### ***Is there any reason to choose one vaccine over another for pregnant or breastfeeding populations?***

At this time, we only know specifics around mRNA Covid-19 vaccines (Pfizer and Moderna), although it is likely that some vaccines will have advantages over others in specific populations. ACIP has advised that pregnant and lactating women **may** receive the mRNA COVID-19 vaccine. A conversation between the patient and their healthcare provider may help the patient with the decision about taking the vaccine.

### ***Should individuals receive the COVID-19 vaccine if they are breastfeeding?***

There are no data on the safety of COVID-19 vaccines in breastfeeding people or the effects of mRNA vaccines (like the Pfizer or Moderna vaccine) on breastfed infants. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated. A conversation between the patient and their healthcare provider may help the patient with the decision about taking the vaccine.

## Pharmacies

### ***Where do pharmacists fit into the distribution plan?***

Pharmacists are currently being onboarded to provide COVID-19 vaccines, with priority going

to onboarding those pharmacies with existing relationships with long-term care facilities and those in counties with no access to vaccines outside of county health departments.

***For approved pharmacy providers, is vaccine anticipated to only go to CVS/Walgreens? Or will approved independent pharmacy providers be included?***

We welcome participation from independent pharmacy providers and strongly encourage them to register as providers. To register as a pandemic vaccine provider, fill out this [survey](#).

***Does Tennessee allow bulk uploads of applications for providers with multiple locations, such as chain pharmacies?***

Unfortunately, each site requires its own Section B of the CDC Provider Agreement.

## Long Term Care Facilities

### ➤ ***Why are some assisted living facilities or residential homes for the aged not being scheduled to receive vaccine now?***

TN has activated Phase A of the Federal Pharmacy Partnership, which starts by vaccinating nursing homes and skilled nursing facilities. This will provide vaccine to NH/SNF staff and residents (though if staff arrive at a health department as a Phase 1a1 individual, they should not be turned away).

TN is expecting to activate Phase B, which includes assisted living facilities and residential homes for the aged, approximately mid-January as vaccine is allocated through the federal government.

***Why is Pfizer vaccine going to hospitals and Moderna vaccine to Long Term Care Facilities (LTCF)? I read Pfizer had a more robust response in the >65 population than Moderna.***

Pfizer vaccine will be positioned in large hospitals due to the challenging requirement of ultra-cold freezer storage, the large quantity of minimum doses per order, and the restricted number of doses available.

***Are assisted living/retirement facilities defined as Long Term Care Facilities?***

LTCFs are defined as nursing homes/skilled nursing facilities, assisted living centers, residential homes for the aged, residential centers for individuals with intellectual and developmental disabilities and group homes.

***We are a Long-Term Care Facility. If we apply to become a pandemic vaccine provider, are we guaranteed to get vaccines?***

At this time, there is no plan to position the vaccine in LTCFs. Staff and residents of LTCFs will be vaccinated through the federal partnership with Walgreens/CVS, through agreements with

local pharmacies, or health department vaccination teams.

***If we receive the vaccine, will we get into long term care facilities to see family?***

There is currently no federal guidance on this issue.

***How will LTCF know which staff will be vaccinated first if there is not enough for everyone?***

Staff in Phase 1a1 who are  $\geq 65$  years of age or staff undergoing current treatment for cancer or who have been diagnosed with diabetes type 1 or 2, coronary artery disease or other serious cardiac disease (excluding high blood pressure), chronic kidney disease, sickle cell anemia (excluding sickle cell trait), chronic obstructive pulmonary disease (COPD), obesity with BMI  $\geq 30$  and those with history of solid organ transplant should be prioritized to be the first to receive COVID-19 vaccines.

Residents and staff with documented acute SARS-CoV-2 infection in the preceding 90 days may choose to delay vaccination until near the end of the 90 day period in order to facilitate vaccination of those who remain susceptible to infection, as current evidence suggests reinfection is uncommon during this period after initial infection.

***Is there any guidance on LTCF residents with immunocompromised conditions receiving vaccine?***

Immunocompromised individuals may receive the vaccine. Immunocompromised individuals were included in clinical trials for both Pfizer and Moderna vaccines, though they may not mount the same level of protection in response to the vaccine as those who are not immunocompromised.

***How do the facilities know if they signed up correctly to be partnered with either CVS/Walgreens?***

If your facility is a CMS-certified long-term care facility and currently reports data through the National Healthcare Safety Network (NHSN), please log in to NHSN via the SAMS portal (<https://sams.cdc.gov>) and look for the link to the Pharmacy Partnership Program under Alerts. You will **not** receive a confirmation email after enrolling. CDC will communicate this information to your chosen pharmacy provider. When it is time to schedule on-site clinics, CVS or Walgreens will reach out directly to your facility to coordinate the event. If you have remaining questions about your pharmacy partner, you can contact the Tennessee Pharmacists Association (at [Covid19@tnpharm.org](mailto:Covid19@tnpharm.org)) for more information.

***If you have a resident scheduled to take the vaccine and they test positive a few days prior, should they wait and take the vaccine later or can they take it as scheduled?***

They should wait to take the vaccine. According to CDC, vaccination of individuals with current SARS-CoV-2 infection should be delayed until the person has recovered from the acute illness

(if they had symptoms) and [criteria](#) have been met for them to discontinue isolation. There is no recommended minimum interval between infection and vaccination, [current evidence](#) shows that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

***Is consent required for vaccination? If we choose to get consent, which form should we use?***

Written consent is not required. Federal law requires the Emergency Use Authorization information sheet to be provided to individuals before vaccination.

If you choose to obtain consent, there is a sample consent form available on the COVID-19 Vaccine Provider Website, linked [here](#). The Pharmacy Partnership Program will provide their own consent forms.

***Will facilities need a provider agreement with the pharmacy administering the vaccine?***

No. If a facility opts into the Pharmacy Partnership Program, they do not have to sign a CDC COVID-19 Vaccination Program Provider Agreement. CVS or Walgreens staff will be responsible for administering the vaccine and signing the agreement.

However, if a facility will be involved in vaccine administration after the Pharmacy Partnership Program ends (e.g., for staff or for new residents), then a provider agreement must be signed with their state.

***Is vaccination recommended for recovered residents and staff who have already had COVID-19?***

According to the CDC, individuals previously diagnosed with acute SARS-CoV-2 infection in the past 90 days may elect to delay vaccination as data suggest that reinfection is unlikely during that period. However, there is no harm in getting the vaccine if patients or staff have already had COVID-19 and prior infection is not a contraindication to vaccination. Testing for antibodies prior to vaccination is not recommended. Specific information for the mRNA vaccines is available from ACIP [here](#).

***Will the Pharmacy Partnership Program staff coming onsite to facilities be tested for COVID prior to each clinic and be in full PPE?***

The Pharmacy Partnership Program for Long-term Care (LTC) Program will facilitate safe vaccination of this critical patient population. Participating pharmacies in the federal pharmacy partnership will be tested according to CMS [guidance](#), and TDH is communicating testing requirements to independent pharmacies as well.



***For short stay residents receiving the vaccine, is there a provision for them to receive the 2nd dose if they have been discharged?***

If they are present in a LTCF but are a short-stay resident, they can go to a local health department at the time of their second dose to receive vaccine.

***Will facilities be required to submit any data regarding COVID-19 vaccine into NHSN?***

Not that we are aware of at this time. The only requirement is that vaccines be reported into TennHIS.

***How will PCR testing be carried out after residents are vaccinated?***

At this time, CMS guidance is unchanged regarding testing for staff and residents. There may be updates to this guidance in the future, but until then, testing should continue as it is currently.

***Will Pharmacy Program staff be tested before entering our facility to perform vaccination clinics?***

Yes, all pharmacy partner staff must be tested following the CMS testing guidance in [QSO-20-38-NH](#) (at the cost of the pharmacy partner, not facility).

## **Outpatient Healthcare Clinics / Primary Care Clinics**

***Are all outpatient physicians in the Phase 1a2 group?***

Yes, outpatient healthcare providers are included in group 1a2. There is no pre-approval process to be included in this group. Vaccines for those in 1a2 will be made available at local health departments and through partnerships with other local stakeholders. All county health departments are focused on providing vaccine to group 1a1 at this time and will transition to 1a2 as they complete 1a1. Note this means that counties will progress through the phases at different paces. More information about various locations to get the vaccine for this group will be made publicly available as soon as possible.

***How are healthcare workers not working in hospitals to be notified when they will be vaccinated? Do we check with the Local Health Department?***

Healthcare workers not working in hospitals will be vaccinated in Phase 1a2—most likely in mid-late January. TN Department of Health will begin sending communication on Fridays through TN Health Alert Network messaging systems with information for the following week.

***What specifics are taken into consideration regarding the patient population for healthcare clinics?***

All healthcare workers are in Phase 1. Hospital workers are sub-prioritized as Phase 1a1 to maintain critical hospital infrastructure.



***Who will determine when smaller, non-hospital healthcare facilities will be able to vaccinate their staff and how?***

Phases are informed by federal guidelines, the Unified Command Group, and Tennessee's COVID-19 Vaccine Stakeholder Group. Outpatient healthcare facility staff are included in Phase 1a2.

***Where do outpatient primary care and family practice health clinics fall in the vaccine allocation Phases? We are typically the first ones to see patients and test due to symptoms.***

Outpatient healthcare is in Phase 1a2. Staff will most likely be vaccinated through events held by county health departments [and through partnerships with other local facilities or partners](#). Clinics may also register to receive vaccine allocations to assist with vaccinating the general public. To begin the registration process, visit the [COVID-19 Vaccine webpage](#) and complete the survey and other requirements listed under COVID-19 Vaccine Partners Onboarding and Regulation section.

***Is there a plan to vaccinate family members of the same household of healthcare workers sooner, or do family members fall into individual risk groups?***

Family members of healthcare workers will be included in phases according to their individual risk.

## **General Vaccine Distribution Questions**

***Will the distribution be affected by "hot-spots"? Or is it strictly population/vulnerability?***

At this time, there is no plan to distribute vaccines according to "hot spots" as the majority of the State is significantly affected, regardless of population.

***Our hospice covers 13 counties and 6 offices. We don't have an application for allocation directly to us. Should we try to get one or go through current distribution channels?***

It would depend upon the ability of your organization to appropriately store, monitor, and report vaccines. Moderna vaccine requires a freezer and a stand-alone refrigerator that is used only for vaccines (no food, etc). Most likely, staff will need to be vaccinated through PODs (Points of Dispensing) or an arrangement with a local health department, hospital, or strike team.

***Does the system guarantee that those who get the first dose also get the second of the same vaccine?***

Tennessee plans for those who get dose one also to get dose two. However, it is possible that anticipated doses may not be received by the State, which could impact the ability to get the

second dose on time.

***Will Health Departments receive the Pfizer vaccine once the production of vaccines ramps up?***

It is possible that local health departments could receive Pfizer vaccine at some point, but that is not the current plan.

***We are a critical access hospital and we were told a strike team would bring us a vaccine. Will that likely be the Moderna vaccine?***

The staff of critical access hospitals who will be vaccinated through public health strike teams will receive the Moderna vaccine.

***Will CPS investigators with DCS who must visit children's homes be included as first responders?***

At this time, CPS investigators are not considered first responders.

***Will vaccine go directly to university student health centers?***

Student health centers are encouraged to register as COVID-19 vaccine providers. If they meet the requirements to receive the vaccine on-site, they will receive allocations when the appropriate phase opens.

**Prioritized Populations and Phased Allocation**

***How will we know when Tennessee moves to the next phase?***

Phases are fluid and will differ by county and, sometimes, by the facility. Information will be sent through many channels to inform individuals of when they can receive the vaccine.

***Is there an anticipated timeline for the phases?***

Movement through phases relies heavily on uptake of vaccine and allocation from the federal government.

***When we move into Phase 1b, where will patients receive the vaccine?***

The definition of the populations within Phase 1b is still fluid, but we will be partnering with our stakeholder group to help communicate these notifications.

***Is there a time frame for vaccinating children under age 12?***

A clear time frame is not known at this time. Pfizer added children under the age of 12 to their clinical trials in November, so we anticipate learning more about this sometime next year as clinical trials progress.

***Will geriatric units' patients and staff in behavioral health facilities receive the vaccine as Phase 1a1?***

Hospital staff will be vaccinated in Phase 1a1. If the geriatric unit is functioning as a long-term care facility, and these individuals are not expected to return to their homes, we would consider those residents as Phase 1a1. Please reach out to [VPDIP.pandemic@tn.gov](mailto:VPDIP.pandemic@tn.gov) so we can best assist.

***Is there going to be more information for organizations to help sub-prioritize their staff? For example, first responders often do not have comorbidities described in the sub-prioritization list. Are there any other criteria we could give them to help sub-prioritize?***

Phase 1a1 of the plan sub-prioritizes those ages  $\geq 65$  years and those with current cancer

treatment, COPD, diabetes, serious heart disease, history of solid organ transplant, sickle cell disease, obesity with BMI  $\geq 30$ , and chronic kidney disease. Once those individuals in Phase 1a1 have had the opportunity to receive the vaccine, the remainder of Phases 1a1 will be offered the vaccine.

***Do university student health center workers who are actively testing for COVID-19 fall under high exposure healthcare workers or other healthcare workers?***

University student healthcare center staff are included in Phase 1a1.

***Where do college healthcare workers and college students fit into the allocation plan?***

College healthcare workers are included in Phase 1a1. College students will likely be included in Phase 3 or Phase 4 unless an individual qualifies for an earlier phase. Phases 3 and 4 are not yet final.

***As a public health officer at a University, we host weekly COVID-19 testing events for our students, faculty, and staff. How should I go about getting our university test site workers vaccinated?***

The staff of mass-testing sites will be vaccinated in Phases 1a1 and will likely receive the vaccine through local health department events. Check with your county health department for more information.

## **Post-Vaccination**

***How quickly is the vaccine effective after receiving it?***

Phase 3 clinical trials suggest:

- Pfizer vaccine is 95% effective at preventing illness from COVID-19 after 14 days from the second dose of vaccine. Pfizer vaccine also provided limited protection after the first dose (52%). Information on the clinical trial for providers can be found [here](#).
- Moderna vaccine is 94.5% effective at preventing illness from COVID-19 after 14 days from the second dose of vaccine.

***People are assuming that a mask does not have to be worn after vaccination. Is there any information stating a mask must be worn after vaccination?***

All current guidelines state to continue to use the same precautions individuals have always practiced to prevent COVID-19—wash hands, self-isolate and get tested if sick, limit interactions with those outside of your household, and wear a mask when with those outside of the household if social distancing cannot be maintained. When in public, be sure to continue to protect yourself by wearing a face covering, watching your distance, and avoiding crowds.

***Is the vaccination an annual vaccine?***

This is not yet known.

## General Questions

### ***Can the V-safe program be used to remind patients to get their second vaccine via text?***

Yes, the V-safe program does provide text reminders for the second dose. **V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after individuals receive a COVID-19 vaccination. Additional information on V-safe is available [here](#).

### ***Will administration cost be billed to patient insurance?***

Administration costs may be billed to insurance, but patients will not be responsible for those charges.

### ***Do you know when the training tutorials will be released for the vaccines? I have heard there is one on receiving, one on administering.***

CDC has created a new, web-on-demand, self-paced module for healthcare providers who will be administering COVID-19 vaccine. This module will provide healthcare providers with information about COVID-19 vaccine Emergency Use Authorization and safety, as well as general information about vaccine storage, handling, administration, and reporting available [here](#).

### ***Should pediatric practices register to be a COVID vaccine provider?***

Yes! Pediatric practices can vaccinate parents, grandparents, patients over age 18 years old (for Moderna vaccine), and staff. Please register to assist with vaccinating the general public!

### ***Has the Pfizer vaccine allocation been reduced in Tennessee due to cold chain issues?***

Pfizer vaccine allocation to Tennessee is based on the State's population. Tennessee generally receives 2% of the federal allocation.

### ***What are the definitions of high-risk and moderate-risk comorbidities?***

These are detailed in the [Tennessee COVID-19 Vaccine Plan](#).

### ***➤ How will we document or prove comorbidities as people present for vaccination?***

Regarding age, it is reasonable to ask individuals to see a form of identification or date of birth at time of vaccination. It is also reasonable to ask individuals to verify employment using a badge or employer letter to confirm they fall into the Phase being vaccinated. Chronic or medical disease is much more challenging to verify on-site at the time of vaccination and this may rely on an honor system to facilitate equitable vaccination distribution. It is not appropriate to ask individuals protected health information at time of vaccination.